IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

CHARLES CONN, *et al*,	§	
	§	
Plaintiffs,	§	
VS.	§	CIVIL ACTION NO. 4:14-CV-298
	§	
C.R. BARD, INC, *et al*,	§	
	§	
Defendants.	§	

ORDER

Before the Court is a Motion for Summary Judgment filed by Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc. (hereinafter "Bard") (Doc. No. 66). The Plaintiff Charles Conn ("Conn") responded (Doc. No. 95), and Bard replied thereto (Doc. No. 109). After this Court made several summary-judgment rulings (*see* Docs. No. 185 & 304), Conn and Bard each filed supplemental briefing (Docs. No. 319 & 320, respectively) on the remaining issues in the Motion for Summary Judgment. Having considered the briefings and applicable law, the Court hereby **GRANTS** Bard's motion as to Conn's strict liability design defect claim ("Third Cause of Action," Doc. No. 1 at 29–30), and **DENIES** the motion as to his strict liability failure to warn claim ("Second Cause of Action," Doc. No. 1 at 28–29).

As a result, this case is set for trial by jury in accordance with the schedule already outlined by the Court. The trial will proceed in two phases, pursuant to this Court's bifurcation order (Doc. No. 116). In Phase I, the jury will determine Bard's liability under a strict liability theory of failure to warn, as well as Conn's entitlement to compensatory damages and the availability of punitive damages. Should the jury find in favor of Conn on the last issue, in Phase II the jury will determine the appropriate amount.

I. Background

This is a personal injury action involving the G2 Filter (the "Filter"), a medical device manufactured and distributed by Bard. The following factual summary is, for the most part, undisputed. On August 23, 2006, 19-year-old Conn saw his gastroenterologist for severe Crohn's disease symptoms. (Doc. No. 66-2, Ex. A at CONCC_AUSG_MDR0040–41). His doctor referred him to the emergency room due to suspicion that he had a thromboembolic disease, or, in layman's terms, problems related to blood clots. (*Id.*). At the South Austin Hospital emergency room, he not only presented with Crohn's-related gastrointestinal symptoms, but also with shortness of breath, high fever, worsening chest pain, and a history of weight loss. (*Id.* at CONCC_CSDSH_MDR00203). His doctors discovered a large free-floating caval thrombus—a blood clot in his inferior vena cava (IVC), and a possible pulmonary embolism. (*Id.* at CONCC_CSDSH_MDR00255). Several different doctors evaluated Conn's condition and recommended the filter placement to help prevent these clots from severely injuring or even killing him. Due to his already existing medical problems, Conn could not take anticoagulants (blood thinners), which are in many cases an accepted alternative treatment for blood clots and pulmonary embolisms. Anticoagulants were contraindicated due to his severe Crohn's disease. (*See id.* at CONCC_CSDSH_MDR00197; MDR00205; MDR00208; MDR00255).

On August 24, 2006, Dr. Michael Gunlock performed a "suprarenal" filter placement due to the "large free-floating caval thrombus" which "precluded infrarenal cava filter placement." (*Id.* at CONCC_CSDSH_MDR00255). According to Dr. Gunlock, one of the reasons he used a Bard G2 filter was because, due to Conn's young age, he intended the filter to be removable. (*Id.*; *see also* MDR00200). This was not the usual location for placement of an IVC filter, but Dr. Gunlock

placed it there in order to avoid "the very large free floating thrombus that was present in the infrarenal cava." (Gunlock Dep. at 27:5–28:23, June 15, 2020). At the time, both the location at which Dr. Gunlock placed the filter and the use of a G2 filter as a retrievable filter were "off label," but both were done due to Conn's precarious condition. While the G2 was designed as a retrievable filter, it was not approved for that indication until after Conn's implantation. (*See* Doc. No. 208-5 at 6–7). Dr. Gunlock's hospital note indicates he thought the filter should be evaluated for removal in three to nine months. (Gunlock Dep. at 48:6–17, June 15, 2020).

On August 28, 2006, just four days after this procedure, Conn was re-admitted to the emergency room at South Austin Hospital because he felt sharp pain in the lower right quadrant of his abdomen and had a dull ache in his swollen right leg. (Doc. No. 66-2, Ex. A at CONCC_CSDSH_MDR00014). After a CT scan, doctors noted that the clots had moved and at least one was extending through and above the recently placed filter. "Before he only had mild extension into the right iliac with no occlusion and he now has complete occlusion of both iliac veins." (*Id.* at CONCC_CSDSH_MDR00015). Given the severity of his condition, the doctors decided to go ahead and put him on an anticoagulant, despite his Crohn's disease. (*Id.*; *see also* CONCC_CSDSH_MDR00010).

On October 31, 2007, Conn was again seen for Crohn's-related symptoms as well as for a check up on his filter placement. (*Id.* at CONNC_STDMC_MDR00667). His treating physician referred him to a different radiologist, and after imaging, the radiologist noted in Conn's medical record:

> The filter is positioned considerably obliquely and appears to be well above the renal vein level. *As that filter appears to be a removable type.* Further evaluation of the filter position is recommended. Consider venocavogram and possible filter removal . . . .

> Addendum: Prior filter deployment images obtained from 8/24/06 demonstrate that the filter has migrated slightly into the tilted position but that it is at the approximate same axial level. *View of the recent CT images suggests that the struts are well implanted into the wall of the vena cava and left renal vein, and the positioning of the struts suggests that the filter is functional . . . At this point this filter is probably not retrievable based on the time that it has been implanted and the angulation of the tip.*

(*Id.* at CONNC_STDMC_MDR00747) (emphasis added). The referring physician conferred with the radiologist and summarized:

> There was some question about the placement of the filter. Apparently it had rotated in the IVC. I reviewed this with the radiologist who after reevaluating felt that the *position was adequate, it was stable and would not embolize from this position and afforded adequate protection for thromboembolic clots in the present orientation.*

(*Id.* at CONNC_STDMC_MDR00667) (emphasis added).

In 2007 and again in 2009, Conn underwent colon and rectal surgery to mitigate the problems he was having due to his Crohn's disease. (Doc. No. 95 at 10 & Doc. No. 95, Ex. 48). On September 19, 2012, Conn again presented to the emergency department—this time at Memorial Hermann Hospital in Houston. (*Id.*, Ex. 7). He complained of abdominal pain, nausea, vomiting, and loss of appetite, and was admitted. (*Id.*, Ex. 3). During the hospital admission, Conn learned there was "a piece of the filter that had broken off and gone to my heart." (*Id.*). He followed up on October 4, 2012, when his physician described the situation as an "IVC filter barb dislodgment to heart." (Doc. No. 66-2, Ex. A at CONNC_UTP_MDR00003).

On January 28, 2017, Conn underwent a filter retrieval attempt "due to severe filter angulation." He complained of pain when the physician tried to dislodge the filter, despite being under sedation. (Doc. No. 95, Ex. 8). The attempt was unsuccessful. (*Id.*). On July 7, 2017, Conn underwent a second, more successful retrieval attempt at Stanford University, performed by Dr. William Kuo. The physician noted: "Today, he is aware of an old filter fragment that has migrated

into his heart . . . . He reports intermittent episodes of chest pain/tightness which he has attributed to his filter in the past." Dr. Kuo performed a partially "successful complex retrieval of a suprarenal Bard G2 IVC filter" and a "successful complex retrieval of a fractured arm fragment," but "an old fractured arm [of the filter] fragment is seen over the right heart unchanged in position compared to prior radiographs." (Doc. No. 66-2, Ex. A at CONNC_SHC_MDR00047). In other words, a piece of the filter remains lodged in Conn's heart.

Prior to both filter retrieval attempts, Conn sued Bard on February 7, 2014 alleging negligence, failure to warn, design defects, manufacturing defect, breach of implied warranty of merchantability, negligent misrepresentation, and loss of consortium on behalf of Plaintiff Alyssa Conn, his wife. He also sought punitive damages. Alyssa Conn's claim, as well as the negligent misrepresentation, breach of warranty, and manufacturing defect claims, have been dismissed with prejudice. (Doc. Nos. 35 & 185).

Bard filed a Motion for Summary Judgment (Doc. No. 66). This Court granted in part the motion as to any claims that the Filter caused blood clot problems or any other related injuries from that time period because they are time-barred. (Doc. No. 185). In a later order, this Court granted in part the motion as to the rest of Conn's negligence claims. (Doc. No. 304).

Supplemental briefing was then filed (Docs. No. 319 & 320) on the remaining issues in the Motion for Summary Judgment. Conn's remaining causes of action for strict liability—design defect and failure to warn[1]—are the subject of this final order on summary judgment.

[1] Conn originally pled an additional cause of action in strict products liability, manufacturing defect ("Fourth Cause of Action," Doc. No. 1 at 30–31), but this and several other claims were later voluntarily withdrawn (*see* Doc. No. 95 at 24; Doc. No. 185 at 5). As a result, only the strict liability claims for design defect and failure to warn (Second and Third Causes of Action, *see* Doc. No. 1 at 28–30) are presented for this Court's resolution.

II. Legal Standard

Summary judgment is warranted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "The movant bears the burden of identifying those portions of the record it believes demonstrate the absence of a genuine issue of material fact." *Triple Tee Golf, Inc. v. Nike, Inc.*, 485 F.3d 253, 261 (5th Cir. 2007) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–25 (1986)). Once a movant submits a properly supported motion, the burden shifts to the non-movant to show that the Court should not grant the motion. *Celotex*, 477 U.S. at 321–25. The non-movant then must provide specific facts showing that there is a genuine dispute. *Id.* at 324; *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). A dispute about a material fact is genuine if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The Court must draw all reasonable inferences in the light most favorable to the nonmoving party in deciding a summary judgment motion. *Id.* at 255. The key question on summary judgment is whether there is evidence raising an issue of material fact upon which a hypothetical, reasonable factfinder could find in favor of the nonmoving party. *Id.* at 248.

III. Analysis

A. Negligence Claims

As a preliminary matter, Conn suggests that the Court should reconsider its ruling on the negligence claims because it should have considered his unsworn affidavits attached to his summary judgment response; and that if it had, the result would have been different. It is on this basis that Conn suggests his negligence claims should have survived this Court's May 2021 order granting partial summary judgment to Bard (Doc. No. 304). In his supplemental brief he argues

first that the sole reason the Court did not consider certain expert reports (Ex. Nos. 52, 55, 58, 60, 61, & 63) was that they were not sworn. Conn cites for example *Patel v. Tex. Tech*, 941 F.3d 743, 746–47 (5th Cir. 2019) that such a ruling contravenes the 2010 amendments to Rule 56(c). Conn also took issue with this Court's reliance on *Smith v. Palafox*, 728 F. App'x 270, 276 (5th Cir. 2018). The Court first notes this was not the sole reason it granted the summary judgment.

Setting that point aside, Conn's own brief points out the flaw in his current argument where it discusses how courts have interpreted the *Palafox* and *Patel* cases. Conn's brief makes the point that unsworn "evidence" was acceptable except in instances where "the proponent of the expert report did not explain how the report could be reduced to admissible evidence at trial." (Doc. No. 319 at 4 (quoting *DeYoung v. Dillon Logistics Inc.*, No. 6:19-cv-00527, 2021 U.S. Dist. LEXIS 22349, at *10–12 (E.D. Tex. Feb. 5, 2021))). Conn made no explanation at the time the motion was under consideration. It was not until *after* the Court ruled that such an explanation was provided. (*See* Doc. Nos. 317, 318).

Even then, Conn's untimely explanation pertained only to Drs. Allen and McMeeking. Other than Drs. Allen and McMeeking, Plaintiff claimed:

> To the extent that Plaintiff has stated a claim for negligent marketing, labeling, promotion, distribution, and sale that may be independent of Plaintiff's failure to warn and design claims, Dr. Parisian has set forth the standard of care and violations of that standard of care.

(Doc. No. 95 at 38–39). No attempt, either before or after the Court ruled, was made to explain how Dr. Parisian's statements would be admissible. In fact, at the most recent hearing, counsel explained that she may not even be alive. (Doc. No. 350 at 42–43). Thus, by Plaintiff's own standard as set forth in his briefing, the one expert in the warning, labeling, and marketing areas that he argued set the standard of care (that would be necessary to maintain a negligence claim) should not be considered.

Moreover, as a threshold matter, any negligence claim for design defect would fail for the same reasons that Conn's strict liability claim for design defect fails (as discussed *infra*). After all, if Conn cannot make the lesser showing required of a strict liability claim for design defect, then he fails to meet his burden on its analog in negligence. *See Shaun T. Mian Corp. v. Hewlett-Packard Co.*, 237 S.W.3d 851, 857 (Tex. App.—Dallas 2007, pet. denied) (holding summary judgment on negligence claims proper where only basis for negligence was alleged defect in product); *see also American Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 437 (Tex. 1997) ("Absent an alternative design, a claim for negligent design or manufacturing fails as a matter of law.").

Finally, his negligent failure to warn claim failed because, contrary to his present assertion, nowhere in his summary judgment response did Conn set forth evidence of the standard of care as required for a negligence claim. *See American Tobacco*, 951 S.W.2d at 437 ("While strict liability focuses on the condition of the product, 'negligence looks at the acts of the manufacturer and determines if it exercised ordinary care in design and production.'" (quoting *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 384 (Tex. 1995))). In a case like this, expert evidence is required to establish the standard of care. *See FFE Transp. Srvcs., Inc. v. Fulgham*, 154 S.W.3d 84, 91 (Tex. 2004). As with any negligence claim, Conn must establish the (1) standard of care, as well as (2) the conduct that failed to meet that standard of care. While Conn referred this Court in numerous places to the latter, he failed to do so for the former.

Even if the Court considered the unsworn affidavits/reports of Drs. Allen and McMeeking, Plaintiff failed to point the Court to evidence as to the prevailing standard of care as required by the Supreme Court of Texas. *See See FFE Transp. Srvcs.*, 154 S.W.3d at 91 (expert testimony required to establish standard of care in cases "involv[ing] the use of specialized equipment and

techniques unfamiliar to the ordinary person"); *see also Ethicon Endo-Surgery, Inc. v. Gillies*, 343 S.W.3d 205, 212 (Tex. App.—Dallas 2011, pet. denied) (finding expert testimony required to establish standard of care for marketing of surgical stapler); *Hager v. Romines*, 913 S.W.2d 733, 735 (Tex. App.—Fort Worth 1995, no writ) (requiring expert testimony to establish duty of care for aerial application of herbicide to crops). Conn's brief at the time blanketly referred the Court to the hundreds of pages of the MDL reports of Dr. McMeeking. This Circuit has long held that it is not incumbent on a trial judge to search the record to find a fact issue. *See Skotak v. Tenneco Resins, Inc.*, 953 F.2d 909, 915 n.7 (5th Cir. 1992). It is the duty of the respondent to specifically point out the controverting evidence. Conn did not direct this Court to summary judgment evidence that set out the standard of care.[2]

B. Gross Negligence and Punitive Damages

With no negligence cause of action left, Conn's claim for gross negligence accordingly fails. *Nowzaradan v. Ryans*, 347 S.W.3d 734, 739 (Tex. App.—Houston [14th Dist.] 2011, no pet.) ("[I]t is well established that a finding of ordinary negligence is prerequisite to a finding of gross negligence."). The Court notes that this ruling does not necessarily preclude Conn from recovering punitive damages on an alternate theory of liability. *See* Tex. Civ. Prac. & Rem. Code § 41.003(a)(1)–(2); *Toyota Motor Sales, U.S.A., Inc. v. Reavis*, 627 S.W.3d 713, 754–55 (Tex. App.—Dallas 2021, pet. filed); *see also Bellefonte Underwriters Ins. Co. v. Brown*, 704 S.W.2d 742, 745 (Tex. 1986) ("In a proper case, punitive damages are recoverable when the action is one in tort, but as a predicate to recovery the plaintiff must show that he has suffered actual damages." (citing *Doubleday & Company, Inc. v. Rogers*, 674 S.W.2d 751, 753–54 (Tex. 1984))).

[2] The Court also notes that with regard to negligent design defect and negligent failure to warn, it has ruled that Dr. Allen is not qualified to opine in either area as to the standard of care under which a device manufacturer operates. (Doc. No. 313).

C. Design Defect

Turning to Conn's remaining claims, the Court begins with Conn's strict liability claim for design defect. To recover on his design defect claim, Texas law requires Conn to prove that "(1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury for which the plaintiff seeks recovery." *Timpte Industries, Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009). With regard to the second element, a safer alternative design is "one that 'would have prevented or significantly reduced the risk of the claimant's personal injury . . . without substantially impairing the product's utility.'" *Christopher v. DePuy Orthopaedics, Inc.*, 888 F.3d 753, 765 (5th Cir. 2018) (quoting Tex. Civ. Prac. & Rem. Code § 82.005(b)). A "substantially different product" fails to qualify as a safer alternative design. *Id.* at 766.

Conn's initial briefing identifies the following IVC filter designs as safer alternatives to the design of the G2 Filter:

(1) Bard's Simon-Nitinol Filter (SNF) (Doc. No. 95 at 35–36; Doc. No. 319 at 10);

(2) Cook's Gunther Tulip Filter (Doc. 95 at 33); and

(3) various "other IVC filters" of undiscernible identity (*e.g.*, Doc. 95 at 33).

In Conn's letter to the Court in response to its request for more information, Conn narrows its argument to "Bard's Simon-Nitinol ('SNF'), as well as competitor filters," none of which Conn identifies. Addressing each proffered alternative in turn, the Court first evaluates Conn's chief candidate, Bard's own SNF. As Conn points out, the SNF is a predecessor to the G2 whose failure rates are, by some measures (including, Conn contends, those contained in Bard's own internal documentation), lesser than those of successor models such as the Recovery filter (and the G2 by

extension, according to Conn[3]). It is equally apparent, however, that these successor models were designed as *retrievable filters*. The SNF, by contrast, is designed to remain permanently installed in the human body. As a result, Conn cannot point to the SNF, a permanent filter, as an "alternative design" to the G2, a retrievable filter. *See Christopher*, 888 F.3d at 765–66. Indeed, as Dr. Gunlock (the implanting physician) stated in his deposition, the G2 was chosen for Mr. Conn, given Conn's young age, because it was retrievable. (*See* Gunlock Dep. at 48:1–49:1, June 15, 2020). As such, the SNF is a substantially different product.

Although Conn appeared to drop this claim in his latest letter to the Court, the second design identified in his earlier briefing as a safer alternative to the G2 implanted in Conn is the Gunther Tulip filter, which is manufactured by one of Bard's competitors. "[A]ccording to Dr. Allen"—Conn's sole source of information on this point—"both the SNF and the Cook Tulip filter are safer than the G2 and would have been safer for Mr. Conn." (Doc. No. 95 at 33). Dr. Allen has previously been precluded from testifying as to device design in this case, for reasons discussed in a previous order (*see* Doc. No. 313 at 10). He is clearly unqualified to opine on what constitutes a safer design. Consequently, the Court will not consider this conclusory statement. Conn therefore has no expert evidence on this point. Without any expert opinion as to its design, Conn's second alternative fails as a matter of law.

Conn's third alternative fails for the primary reason that Conn has made no attempt to describe these various unidentified "other IVC filters" in any meaningful way, apart from "ha[ving] lower rates of fracture, migration, and perforation than the G2" during the relevant timeframe (Doc. No. 95 at 33). Without any evidence as to the identity or origin of these designs

[3] See, e.g., Doc. No. 95 at 32 ("[A]t the time of implant of Mr. Conn's filter there existed alternative designs for IVC filters, including Bard's SNF, the predicate device used by Bard to obtain clearance of the Recovery, which was then used as the predicate device to obtain clearance for the G2.").

(let alone their risk–utility characteristics), no reasonable jury could find that such "other filters available at the time of Mr. Conn's implant" (Doc. No. 95 at 32) constitute a safer alternative design to the G2. Each "alternative design" identified by Conn thus fails under Texas law. With no other designs offered than the three analyzed here, Conn has failed to meet his burden at the summary judgment stage. Conn's design defect claim accordingly fails as a matter of law.

D. Failure to Warn

The Court next addresses Conn's strict liability claim for failure to warn. In Texas, a plaintiff raising a failure to warn claim must establish, *inter alia*, (1) the absence of a warning that renders the product unreasonably dangerous to the product's ultimate user or consumer, and (2) a causal link between the failure to warn and the product user's injury. *Emerson Elec. Co. v. Johnson*, 601 S.W.3d 813, 825–826 (Tex. App.—Fort Worth 2018, pet. granted), *aff'd*, 627 S.W.3d 197 (Tex. 2021). The learned intermediary doctrine states that, in some situations, a warning to an intermediary fulfills a supplier's duty to warn ultimate consumers. *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 591 (Tex. 1986). Where a case involves a surgically implanted medical device, this doctrine requires product manufacturers to warn doctors implanting the device, not the patient. *Pizzitola v. Ethicon, Inc.*, No. 20-cv-2256, 2020 WL 6365545, at *6 (S.D. Tex. Aug. 31, 2020) (citing *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 467–68 (5th Cir. 1999)).

At the outset, the Court observes that Bard's duty to warn extended only to Dr. Gunlock, Conn's treating physician, and not to Plaintiff himself. *See id.* Adequate warnings are "those given in a form that could be reasonably expected to catch the attention of a reasonably prudent" physician. *Bean v. Baxter Healthcare Corp.*, 965 S.W.2d 656, 664 (Tex. App.—Houston [14th Dist.] 1998, no pet.). The question whether warnings are adequate is normally a fact question for the jury, but the Fifth Circuit has held that where "a warning specifically mentions the

circumstances complained of, the warning is adequate as a matter of law." *Ackermann v. Wyeth Pharms.*, 526 F.3d 203, 208 (5th Cir. 2008) (quoting *McNeil v. Wyeth*, 462 F.3d 364, 368 (5th Cir. 2006)).

In its Motion for Summary Judgment, Bard argues that the warnings contained in the G2's Instructions for Use (IFUs) were adequate as a matter of law. (Doc. No. 66 at 18–22). The IFUs accompanied the G2 filter implanted in Conn and were reviewed by Dr. Gunlock prior to implantation. (Gunlock Dep. at 71:4–7, June 15, 2020). Bard's IFUs contained the following "Warnings" section with respect to implantation of the G2 filter:

E. Warnings

***G2* Filter Implantation**

1. **The *G2* Filter is pre-loaded and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the *G2* Filter cannot be safely reloaded.**
2. **Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution # 4).**
3. **If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.**
4. **Never advance the guidewire or introducer sheath/dilator or deploy the filter without fluoroscopic guidance.**
5. **Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.**
6. **Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots, and/or dislodgment due to large clot burdens.**
7. **Never use the jugular or subclavian delivery system for femoral approach, as this will result in improper *G2* Filter orientation within the IVC.**
8. **When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 800 psi.**
9. **Persons with allergic reactions to nickel may suffer an allergic response to this implant.**
10. **After use, the *G2* Filter system and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.**

Reference Potential Complications section for further information regarding other known filter complications.

(Doc. 66-7 at 4). In the "Potential Complications" section, the IFUs go on to state:

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to, the following:

- Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots, and/or dislodgment due to large clot burdens.
- Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae
- Perforation or other acute or chronic damage of the IVC wall.
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels.
- Caval thrombosis/occlusion.
- Extravasation of contrast material at time of venacavogram.
- Air embolism.
- Hematoma or nerve injury at the puncture site
- Hemorrhage.
- Restriction of blood flow.
- Occlusion of small vessels.
- Distal embolization.
- Infection.
- Intimal tear.
- Stenosis at implant site.

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

Id. at 5.

Defendant Bard argues that these sections, taken together, "would have accurately informed a reasonably prudent physician of the risks associated with the [G2] Filter." (Doc. No. 66 at 27). Moreover, Bard argues, apparently uncontested, that Conn was warned of the very complications that he later experienced—fracture, movement or migration, embolization, and perforation. Indeed, Dr. Gunlock talked about these risks with Conn prior to the procedure (Gunlock Dep. at 43:16–23, June 15, 2020), and Conn signed an informed consent form. (Doc. No. 66-2, Ex. A at CONNC_CSDSH_MDR00377-378). Therefore, Bard contends, with some justification, that the failure to warn claim must fail as a matter of law. *See Ackermann*, 526 F.3d at 208.

In response, Plaintiff submits that Bard's warnings were defective because the IFUs fail to provide physicians with a fair indication of the nature and extent of the dangers posed by the G2 Filter. (Doc. No. 95 at 25–30). Conn argues that Bard's warnings failed to adequately convey the risks of implanting Bard's retrievable filter designs (including the G2) in favor of comparatively less dangerous models. These risks, Conn argues, were known to Bard in the form of comparative failure rate data. In this vein, Conn points to various Bard internal documents, including data tending to illustrate disproportionate failure rates of Bard's G2 filters. (*See* Doc. No. 95 at 18) (citing BPVE-01-01510717) (2005 spreadsheet entitled "MAUDE Data Through Q3 2005" reporting a perforation failure rate for the G2 Filter approximately 15 times that of the SNF); (*id.*) at 19 (citing BPVEFILTER-01-00008355) (February 2006 Health Hazard Evaluation concluding the severity of G2 Filter migration events is "critical"); (*id.*) (citing BPVE-01-00720854) (March 2006 presentation entitled "G2 Caudal Migration Update" describing failure rate as "[u]nacceptable risk per FMEA").

In reply, Bard argues that Conn has also failed to establish causation, to which Conn points to the deposition of Dr. Gunlock. Dr. Gunlock was asked about the importance of comparative failure rate data in his decision to use Bard's G2 filter:

> Q: And at any point in time, did Bard disclose to you that its IVC filters were fracturing at a greater rate than other IVC filters?
> A: No.
> . . . .
> Q: Would this have — information have been important to you to know?
> A: Yes.
> Q: And could it have affected your decision to use Bard filters versus — versus others at that time?
> A: Yeah, the answer is yes to that particular filter. Not necessarily I would exclude everything that Bard makes at the time, just that filter because there were other, I think, Bard filters at that time, so, like, the Simon Nitinol [SNF] I think was still available if I recall at that time.

> So the answer is, yes, if — if you're talking about the — the G2 filter or the — the rig — the original Recovery, the answer is yes, I would have liked to have known that information.

(Gunlock Dep. at 75:19–22, 76:16–77:5, June 15, 2020). Moreover, Conn states in his declaration that he would not haven given consent for the G2 to be implanted had he been apprised of its higher rates of complications. (Doc. No. 95-3 at 2).

When the Court views the foregoing statements by Dr. Gunlock and Conn, along with the other related summary judgment evidence, in the light most favorable to the nonmovant (as this Court must in a summary judgment context), it finds the existence of a genuine issue of material fact as to the adequacy of Bard's warnings and causation. *See Anderson*, 477 U.S. at 248. Plaintiff Conn has accordingly met his burden on his strict liability failure to warn claim at the summary judgment stage.

IV. Conclusion

For the foregoing reasons, the Court **GRANTS** in part and **DENIES** in part Bard's Motion for Summary Judgment. Conn's design defect claim is hereby dismissed with prejudice.

Accordingly, the sole cause of action to be tried in this case is Conn's strict liability claim for failure to warn.

Signed at Houston, Texas, this 13th day of October, 2021.

Andrew S. Hanen
United States District Judge